UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,982	02/02/2006	Fariello Ruggero	373987-011US (102895)	6583

37509 7590 09/17/2009

DECHERT LLP
P.O. BOX 390460
MOUNTAIN VIEW, CA 94039-0460

EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

napatentdept@dechert.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,982	RUGGERO ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-68* is/are pending in the application.

4a) Of the above claim(s) *68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/24/09 (5 entries)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on June 24, 2009. Claim(s) 57-68 are pending. Claim(s) 57-68 have been added. Claim(s) 1-56 have been cancelled. Claim(s) 68 is withdrawn from further examination as it is drawn to a non-elected invention. Claim(s) 57-67 are examined herein.

Response to Arguments

In view of Applicant's cancellation of claim 17, the objection is hereby withdrawn.

In view of Applicant's amendments/cancellation of claims 1, 2, 8-10, 13-19, and 27, the 112 1st paragraph rejection is hereby withdrawn.

In view of Applicant's amendments/cancellation of claims 1, 2, 8-10, 13-19, and 27, the 112 1st written description rejection is hereby withdrawn.

In view of Applicant's amendments/cancellation of claims 13 and 14, the 112 2nd rejection is hereby withdrawn.

In view of Applicant's amendments/cancellation and affidavit submitted 6/24/09, the 102(b) rejection of claims 1, 2, 18, 19 as being anticipated by Fredriksson et al. (*Journal of Neural Transmission*, 1999) is hereby withdrawn.

In view of Applicant's amendments/cancellation, the 103(a) rejection of claims 8, 9, 10, 13, 14, and 17 as being unpatentable over Fredriksson et al. (*Journal of Neural*

Transmission, 1999) as applied to claims 1, 2, 18, 19 above in view of Edgren (US Patent No. 6,217,905 B1), the rejection is hereby withdrawn.

In view of Applicant's amendments/cancellation, the 103(a) rejection of claims 15 and 16 as being unpatentable over Fredriksson et al. (*Journal of Neural Transmission*, 1999) as applied to claims 1, 2, 18, 19 above in view of Chenard (US Patent No. 6,258,827 B1) is hereby withdrawn.

The following new rejections are set forth on record in the office below as necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) of record and Birkmayer (US Patent No. 3,795,739) in view of Chazot (Current Opinion in Investigational Drugs, 2001) of record.

Dostert teaches N-phenylalkyl substituted α-amino carboxamide derivatives of formula I as therapeutic agents for the treatment of Parkinson's disease (column 1, line 32-column 2, line 7). Specifically, Dostert teaches (S)-2-[4-(3-fluorobenzyloxy)benzyl]aminopropionamide (column 15, lines 3-4) (a.k.a safinamide).

Dostert additionally teaches pharmaceutically acceptable salts thereof of including among others, methanesulfonic acid (column 2, 28).

Dostert teaches that the compounds may be administered orally at doses ranging from about 50 to about 1500 mg/day (column 12, lines 7-10).

Dostert does not teach the coadministration of L-Dopa which is administered in an amount that alone has therapeutic effect.

Birkmayer teaches the treatment of Parkinson's disease with the pharmaceutical composition comprising L-dopa in combination with a peripheral decarboxylase inhibitor (column 1, line 55-column 2, line 5). L-dopa is administered from about 0.1g to about 4g (column 4, lines 3-5). Typical peripheral decarboxylase inhibitors include carbidopa encompassed by the formula in column 2, line 65.

Birkmayer discloses an example whereby the L-dopa therapeutic regimen is administered for an eight week span (column 5, example 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined safinamide, used to treat Parkinson's disease, as taught by Dostert, with a combination of L-dopa and a peripheral decarboxylase inhibitor, as taught by Birkmayer, for the same purpose. The motivation to combine these agents is provided by Chazot. Chazot teaches the coadminstration of safinamide with that of L-dopa in the treatment of Parkinson's disease.

Thus, in view of the foregoing art made of record, it would have been obvious to one in the art to have combined L-dopa (with or without decarboxylase inhibitor) with safinamide in the treatment of Parkinson's disease.

Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) and Birkmayer (US Patent No. 3,795,739) in view of Chazot (Current Opinion in Investigational Drugs, 2001) of record as applied to claims 57-64 and 67 above in view of Chenard (US Patent No. 6,258,827 B1).

Dostert and Birkmayer are discussed above.

Neither Dostert nor Birkmayer teach the composition further comprising a catechol-*O*-methyltransferase inhibitor, such as tolcapone or entacapone.

Chenard teaches that there are classes of compounds reported as being useful in the treatment of Parkinson's disease namely, among others, D1, D2 agonists,

monoamine oxidase-B inhibitors, levodopa and COMT inhibitors (column 12, lines 31-45), wherein COMT inhibitors include tolcapone and entacapone (column 13, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the combination of safinamide and levodopa for the treatment of Parkinson's as taught by Dostert and Birkmayer and also administered additional Parkinson's disease agents such as tolcapone or entacapone as taught by Chenard. Because such agents are well known in the art to treat the same disease, it would have been obvious to one in the art to have combined them. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Claims 1, 2, 8-10, 13-19, and 27 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617